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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
THOMAS, COURTNEY D

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/942,528	LANG, PHILIPP	
	Examiner	Art Unit	
	Courtney Thomas	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-50 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 13-31 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inga et al. (U.S. Patent 5,384,643) in view of Fishman (U.S. Patent 5,271,401).

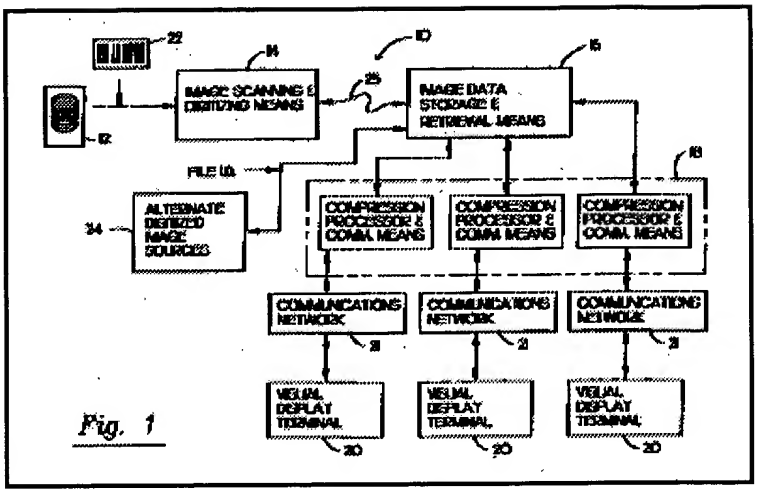
4. 

Fig. 1

5. [57] **ABSTRACT**

A storage, retrieval, and transmission system is configured to provide fast, efficient telecommunication access to digitized images (e.g., medical diagnostic X-ray images) to multiple requesting subscribers. Image data are downloaded, via the telephone lines, to a remote display terminal in an optimal fashion that employs a two-dimensional patterned data compression scheme. The

Figure 1 and Abstract – U.S. Patent 5,384,643 to Inga et al.

6. **As per claims 1 and 48**, Inga et al. disclose a method comprising the steps of providing a digitized X-ray image on a local computer (abstract; column 6, lines 65-68, column 7, line 1); transmitting the X-ray image to a remote computer (abstract; column 7, lines 1-12) and analyzing the data at the remote computer. Inga et al. do not explicitly disclose a method comprising the step of deriving quantitative information of the X-ray image at the remote computer.

7.

DETAILED DESCRIPTION

X-Ray radiological imaging takes advantage of the fact that certain structures within a body attenuate or absorb X-Rays to a greater degree than do other structures enabling an X-Ray image to show certain structures which could not otherwise be seen without surgery or an invasive procedure using a physical instrument, and to provide quantitative functional information based on the degree of contrast present. The X-Ray

U.S. Patent 5,271,401 to Fishman (column 6, lines 1-10)

8. Fishman discloses a method wherein quantitative information of X-ray images is achieved by noting attenuation differences (contrasts) within the image (column 6, lines 1-10).

9. It would have been obvious to modify the method of Inga et al. such that it incorporated the step of determining quantitative information of an X-ray image at a remote computer. One would have been motivated to make such a modification, since quantitative information of X-ray images can be obtained by simply noting the attenuation differences within an X-ray image as taught by Fishman (column 6, lines 1-10).

10. **As per claim 2**, Inga et al. as modified, do not explicitly disclose a method wherein the analysis of the images comprises using a computer program on the remote computer.

11. It would have been obvious to further modify the method of Barnhill et al. such that it incorporated a remote computer configured with a program for analysis of images. One would have been motivated to make such a modification so that a remote computer could carry out automated analysis of received data, thereby providing near instantaneous results of program computations.

12. **As per claims 3-5**, Inga et al. as modified, do not explicitly disclose a method wherein the quantitative information is densitometric information; wherein the densitometric information

is bone mineral density and wherein the densitometric information is the density of selected soft-tissue or organs.

13. It would have been obvious to further modify the method of Inga et al., such that it incorporated the aforementioned limitations. One would have been motivated to make such a modification for the purpose of screening for the occurrence of bone degradation as revealed by the contrasts within X-ray imagery.

14. **As per claims 13-17**, Inga et al. as modified, do not explicitly disclose a method wherein x-ray acquisition parameters are transmitted to the remote computer; x-ray acquisition parameters are transmitted prior to, after or simultaneously with x-ray imaging; wherein x-ray acquisition parameters are selected from a group consisting of x-ray tube voltage, x-ray energy, x-ray tube current, film-focus distance, object-film distance, x-ray collimation, focal spot size, spatial resolution of the x-ray system, filter technique, and film-focus distance.

15. It would have been obvious to modify the method of Inga et al. such that it incorporated the aforementioned limitations. One would have been motivated to make such a modification so that acquisition parameters are correlated with obtained x-ray imagery, thereby enabling a practitioner to devise analyses of the correlated results and to set parameters that produce high quality images.

16. **As per claim 18-20**, Inga et al. as modified, do not explicitly disclose a method wherein the x-ray image further comprises one or more internal standards; the internal standard is density of a tissue of a human or air surrounding a structure and the internal standard is density of a tissue and the tissue is selected from the group consisting of subcutaneous fat, bone and muscle.

17. It would have been obvious to further modify the method of Inga et al., such that it incorporated x-ray images further comprising one or more internal standards representing the density of tissue of a human or air surrounding a structure; the tissue is selected from the group consisting of subcutaneous fat, bone and muscle. One would have been motivated to make such a modification so that areas of interest are easily recognizable within an image, thereby minimizing ambiguity amongst coexisting anatomical structures.

18. **As per claim 21**, Inga et al. as modified, do not explicitly disclose a method wherein the information is encrypted prior to transmission.

19. It would have been obvious to further modify the method of Inga et al. such that information is encrypted prior to transmission. One would have been motivated to make such a modification so that patient information is protected from unauthorized access during transmission via a network or mainframe; thereby preserving the integrity of personal information during transit.

20. **As per claims 22-26**, Inga et al. as modified, do not explicitly disclose a method comprising generating a diagnostic report based on the quantitative information; wherein the diagnostic report provides information on a patient's state of health; wherein the state of health is selected from the group consisting of bone mineral density status and fracture risk; further comprising generating a bill for the diagnostic report and wherein the bill is generated by a computer program on the remote computer.

21. It would have been obvious to further modify the method of Inga et al. such that it incorporated the aforementioned limitations. One would have been motivated to make such a modification so that obtained information is tabulated to reveal the state of a patient's health.

Additionally, it would have been obvious to incorporate administrative documents such as billing information along with the generated diagnostic report. One would have been motivated to make such a modification so that services rendered is documented and provided along with a prognosis.

22. **As per claims 27-29**, Inga et al. as modified, disclose a method wherein the x-ray image is an x-ray film (**12**) and wherein the film is digitized using a scanning unit (**14**) (see Inga et al. - Figs. 1 and 2).

23. **As per claims 30 and 31**, Inga et al. as modified, do not explicitly disclose a method wherein an x-ray film image is digitally acquired using a selenium or silicon detector.

24. It would have been obvious to modify the method of Inga et al. such that an x-ray film is digitally acquired. One would have been motivated to make such a modification so that the additional step of converting an analogue image to a digital image is avoided, thereby reducing the complexity of an image data transmission process. Additionally, practitioners in the radiation art would be well aware of the use of selenium or silicon detectors for digital image acquisition; the selection of either of the aforementioned detectors would be at the discretion of a respective experimenter.

25. Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inga et al. (U.S. Patent 5,384,643) and (U.S. Patent 5,271,401) in view of Arnold (U.S. Patent 5,335,260).

26. **As per claims 6 and 7**, Inga et al. as modified, do not explicitly disclose a method wherein the x-ray image further includes an external standard; the external standard being a calibration phantom.

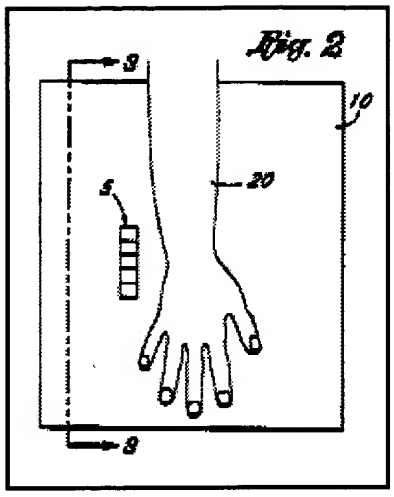
27. 

Figure 2 - U.S. Patent 5,335,260 to Arnold

28. Arnold teaches a method wherein an x-ray image includes an external standard (**5**).

29. It would have been obvious to further modify the method of Inga et al. such that it incorporated an x-ray image including an external standard. One would have been motivated to make such a modification so that x-ray imagery could be quantified for calcium, bone mass and bone density by comparison of x-ray attenuation caused by an external standard to the attenuation caused by the object of interest as taught by Arnold (abstract; column 2, lines 48-54).

30. **As per claims 8-12**, Inga et al. as modified, do not explicitly disclose a method wherein quantitative information is information on the morphology of a structure; the information based on two or three-dimensional arrangements of individual components forming the structure and wherein the structure is bone.

31. It would have been obvious to further modify the method of Inga et al. such that quantitative information is information on the morphology of a bone structure. One would have been motivated to make such a modification so that 2-D or 3-D images of bone structure could

be used to determine whether a problem exists by comparing known structures to obtained images.

32. Claims 32-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiabrera et al. (U.S. Patent 5,917,877).

33.

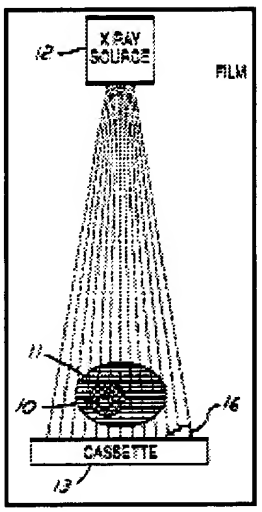


Figure 1 - U.S. Patent 5,917,877 to Chiabrera et al.

34. **As per claims 32, 39, 40 and 47**, Chiabrera et al. disclose an apparatus comprising an x-ray film holder (**13**), X-ray film ((**23**) - Fig. 2) a calibration phantom (**16**) and an x-ray imaging assembly and computer programs, wherein said computer programs analyze and assess bone mineral density (see Fig. 1 above and respective portions of the specification and included Figs.) Chiabrera et al. do not explicitly disclose a calibration phantom comprising a marker in an area of known density; the markers comprising a plurality of geometrical patterns.

35. Chiabrera et al. teach that a calibration phantom can comprise a wedge construction wherein differing heights represent varying thick nesses thereby allowing the distinct identification of wedge attenuating characteristics (column 3, lines 65 through column 4, line 3).

36. It would have been obvious to modify the apparatus of Chiabrera et al. such that it incorporated a calibration phantom comprising a marker in an area of known density. One would have been motivated to make such a modification so that the marker serves as a positioning indicator for the phantom as well as an indicator for the attenuation attributes of the phantom at the indicated position as suggested by Chiabrera et al. Additionally, it is the position of the examiner that the patterning of the markers would not deviate from the scope and spirit of the disclosed invention.

37.

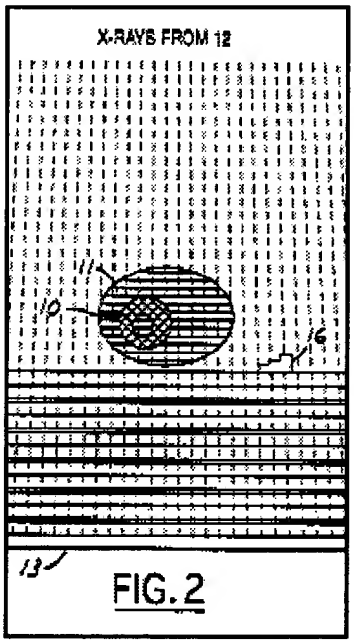


Figure 2 - U.S. Patent 5,917,877 to Chiabrera et al.

38. **As per claim 33**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom (**16**) projects free of bone tissue (Fig. 2, above).

39. **As per claim 34**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom is attached to the x-ray film holder or a detector system (Fig. 1, above).

40. **As per claim 35, 41, 42 and 43**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom is integral to the x-ray film holder included between two physical layers of x-ray film and included within one of the physical layers of the x-ray film (Figs. 1-3).

41. **As per claim 36 and 45**, Chiabrera et al. do not explicitly disclose an apparatus configured as a dental x-ray assembly and wherein the image is a dental x-ray image.

42. It would have been obvious to modify the apparatus of Chiabrera et al. such that it was configured as a dental x-ray assembly. One would have been motivated to make such a modification so that the assembly was configured for image capture and calibration of a particular portion of a patient's anatomy, such as patient's teeth and mandible structure.

43. **As per claim 37**, Chiabrera et al. as modified, disclose an apparatus wherein the calibration phantom comprises a step wedge (Fig. 4).

44. **As per claim 38,** Chiabrera et al. as modified, do not explicitly disclose an apparatus wherein the calibration phantom comprises a plurality of fluid-filled chambers.

45. It would have been obvious to modify the apparatus of Chiabrera et al., such that it incorporated a calibration phantom comprising a plurality of fluid-filled chambers. One would have been motivated to make such a modification so that the phantom would mimic the attenuation characteristics of soft tissue of a human body.

46. **As per claims 44**, Chiabrera et al. as modified, disclose a method comprising providing an assembly according to claim 32, wherein the calibration phantom is positioned such that x-rays pass through a subject and the calibration phantom simultaneously, wherein the calibration phantom projects free of materials that alter it's apparent density (see Fig. 2 above); creating an

image of the phantom and the portion of the subject's anatomy; comparing the image of the phantom and the subject's anatomy to determine bone mineral density of the subject (abstract; columns 1-3, column 4, lines 1-41).

47. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chiabrera et al. (U.S. Patent 5,917,877) in view of Inga et al. (U.S. Patent 5,384,643).

48. **As per claim 46**, Chiabrera et al. do not explicitly disclose a method wherein comparing is performed in a network environment.

49. Inga et al. disclose a method wherein comparison is performed in a network environment (abstract; column 3, lines 17-45).

50. It would have been obvious to modify the method of Chiabrera et al. such that it incorporated the step of comparing performed in a network environment. One would have been motivated to make such a modification so that analysis could be accentuated by the ability to access several image and patient data from an archive source as taught by Inga et al. (abstract; column 3, lines 17-45).

51. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiabrera et al. U.S. Patent 5,917,877) in view of Barnhill et al. (U.S. Patent 6,248,063).

52. **As per claims 49 and 50**, Chiabrera et al. do not explicitly disclose a method comprising administering a suitable treatment; and wherein the treatment comprises administering an anti-resorptive agent or an anabolic agent.

53. Barnhill et al. teach the diagnosis of a disease utilizing a network structure and subsequent application of suitable treatment. Barnhill et al. teach a treatment based on prognosis

of results, wherein treatment is optimized for its efficacy (column 8, lines 12-67, column 9, lines 1-56).

54. It would have been obvious to modify the method of Chiabrera et al. such that it comprised administering a suitable treatment. One would have been motivated to make such a modification so that treatment is optimized for efficacy, ensuring rapid patient recovery and ceasing of disease progression as taught by Barnhill et al. (column 8, lines 12-67, column 9, lines 1-56).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney Thomas whose telephone number is (703) 306-0473. The examiner can normally be reached on M - F (9 am - 5 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (703) 308 4858. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0530.

Courtney Thomas

August 7, 2003

DAVID V. BRUCE
PRIMARY EXAMINER